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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,421

01/22/2004

Paul Ashton

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ROPES & GRAY LLP

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EXAMINER

SASAN, ARADHANA

ART UNIT

PAPER NUMBER

1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/762,421</p>	<p>Applicant(s) ASHTON ET AL.</p>	
	<p>Examiner ARADHANA SASAN</p>	<p>Art Unit 1615</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 December 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1-3, 10, 14, 17, 18 and 21.
- Claim(s) withdrawn from consideration: 4-9 and 11-13.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Aradhana Sasan/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments (filed 12/21/09) have been fully considered but are not found persuasive.

Rejection of claims 1-3, 10, 14, 16-17 under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,378,475) in view of Wong et al. (US 6,331,313) and further in view of Heller et al. (US 3,811,444)

Applicants argue that whether the instant claims require a biodegradable system or not is not relevant. Applicants assert that they are addressing the issue of whether one of skill in the art would have the motivation to combine Smith and/or Wong, which both teach non-bioerodible devices with the teaching of Heller which teaches only bioerodible devices to arrive at a device of the pending claims.

This is not persuasive because instant claims require (i) an inner drug core comprising a carbonic anhydrase inhibitor (CAI) and a matrix material, (ii) a first coating that is substantially impermeable to the passage of the CAI, and (iii) an additional coating permeable to the passage of the CAI and comprising a CAI. Smith teaches an inner core with the active ingredient, a first coating layer that is essentially impermeable to the passage of the active ingredient, and a second coating permeable to the passage of the active ingredient. Instant claims Therefore, the components of the sustained release drug device are taught by Smith. Instant claims do not require a biodegradable system and therefore, the argument with respect to biodegradability is not commensurate in scope with the instant claims.

Applicants assert that neither Smith nor Wong teaches or suggests a device wherein the rate of release of the drug relies on the bioerodibility of the device, and in fact, both Smith and Wong emphasize the importance of non-biodegradability to ensure the desired release profiles. Applicants assert that in view of both Smith and Wong, a person of ordinary skill in the art would be motivated to look to the teachings of non-bioerodible (at least during the term of release) devices in order to obtain linear release of drug.

This is not persuasive because the structural components of the drug delivery device as required by instant claims are taught by Smith, Wong, and Heller (i.e., the inner core comprising the CAI and matrix, the first coating that is substantially impermeable to the passage of the CAI, and the additional coating permeable to the passage of the CAI). The bioerodible polymer matrix would have been obvious over the teaching by Wong that the drug "may also be present as a solution or be dispersed in a polymer matrix. Wong also teaches examples of biodegradable polymers that can be used in the device where "the outer layer degrades after the drug has been released for the desired duration" (Col. 9, lines 43-45 and lines 60-67, Col. 10, lines 1-9). The teaching of Heller is properly combined with the teachings of Smith and Wong because all the prior art references teach a controlled or sustained release drug delivery device suitable for ocular insertion/implantation and one of ordinary skill in the art would find it obvious to incorporate a drug in the outer layer of the sustained release device in order to provide immediate release of the drug (variable drug release from the outer layer of an ocular insert is taught by Heller (Col. 13, lines 5-33)).

Applicants argue that the Office Action merely states that the instant claims are taught by Smith, Wong, and Heller and further that Heller is properly combined with the teachings of Smith and Wong because all of the references teach a controlled or sustained release drug delivery device suitable for ocular insertion.

This is not persuasive because MPEP 2143 states that it is obvious to apply a known technique to a known device (method, or product) ready for improvement to yield predictable results.

Applicants argue that "the Examiner is using impermissible hindsight to combine the cited references despite the fact that both Smith and Wong expressly discourage release of drug through a degradation process as taught by Heller. The mere fact that Smith, Wong, and Heller all teach devices suitable for ocular implantation is inadequate to establish a motivation to combine when the express teachings of each of the references are considered."

This is not persuasive because it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Rejection of claims 18 and 21 under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 5,902,598) in view of Wong et al. (US 6,331,313) and further in view of Heller et al. (US 3,811,444)

Applicants argue that they are addressing the issue of whether one of skill in the art would have the motivation to combine Chen and/or Wong, which both teach non-bioerodible devices with the teaching of Heller which teaches only bioerodible devices to arrive at a device of the pending claims. Applicants argue that Chen teaches away from the use of bioerodible systems for obtaining reliable release rates over extended periods of time. Applicants argue that the office action has provided no motivation to combine the teaching of Heller with the teachings of Chen or Wong and assert that the Examiner is using impermissible hindsight to combine the cited references.

This is not persuasive the components of the sustained release drug device are taught by Chen. Instant claims do not require a biodegradable system and therefore, the argument with respect to biodegradability is not commensurate in scope with the instant claims.

The structural components of the drug delivery device as required by instant claims are taught by Chen, Wong and Heller (i.e., the inner core comprising the CAI and matrix, the first coating that is substantially impermeable to the passage of the CAI, and the additional coating permeable to the passage of the CAI). The teaching of Heller is properly combined with the teachings of Chen and Wong because all the prior art references teach a controlled or sustained release drug delivery device suitable for ocular insertion/implantation and one of ordinary skill in the art would find it obvious to incorporate a drug in the outer layer of the sustained release device in order to provide immediate release of the drug (variable drug release from the outer layer of an ocular insert is taught by Heller (Col. 13, lines 5-33)). MPEP 2143 states that it is obvious to apply a known technique to a known device (method, or product) ready for improvement to yield predictable results. Moreover, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants arguments regarding the obviousness type double patenting rejection have been fully considered. Until such time that a terminal disclaimer is filed and approved, the rejection will be maintained.